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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/346,794	07/02/1999	TERRY P. SNUTCH	NMEDP001-2	2888

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	21

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/346,794	Applicant(s) Snutch et al
	Examiner Nirmal S. Basi	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 7, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *25-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *25-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Amendment filed 2/7/03 (paper number 25) has been entered.

Election/Restriction

2. Applicant's election with traverse of the species of nucleic acid comprising SEQ ID NO:23, in Paper No. 25, is acknowledged. Applicant argues: a) the rationale for requiring election among groups III-V in the previously issued restriction requirement (4 October 2000) is not relevant in the context of the present claims, b) the claims to which this restriction requirement was applied were claims to the α_1 subunit encoding DNA per se, not to methods to identify compounds that agonize or antagonize such receptors and therefore the basis for the restriction requirement is quite different from that imposed herein, c) the three sequences set forth encode different subtypes of a T-type calcium ion channel and since the claims are drawn to a method to identify a compound which behaves as an agonist (or antagonist) for a T-type calcium channel, any one of SEQ ID NO:23, 25 and 27 would be satisfactory in the method, d) since there are only three species an undue burden is not placed on the Office to examine the present claims. Applicants arguments have been fully considered but not found persuasive. The previous restriction requirement was not meant to be constructed as a requirement for election of species. The use of each individual nucleic acid comprising SEQ ID NO:23, 25 or 27 is considered distinct. Therefore, the restriction requirement is not to be construed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention, therefore the use of each member in a method also constitutes an independent and

patentably distinct invention. The claims of elected Group XVI are drawn to a method to identify a compound which behaves as an agonist for a T-type calcium channel by contacting the α_1 subunit of a heterologous T-type calcium channel with a compound, wherein said α_1 subunit is encoded by a nucleotide sequence which hybridizes (under conditions of specific stringency) to a nucleic acid comprising SEQ ID NO:23, 25 or 27. The claims apply to numerous T-type calcium channel α_1 subunits. The nucleic acid comprising SEQ ID NO:23, 25 or 27 are three distinct classes of calcium channel subunits, each an independent and distinct invention. Each of the different nucleic acids encode a distinct polypeptides with distinct structural or functional properties, each one with different agonist or antagonist binding properties. Agonists or antagonists identified , for example, by the use of the polypeptide encoded by a nucleotide which hybridizes to the nucleic acid of SEQ ID NO:23 may not be the same as those identified by the polypeptide encoded by a nucleotide which hybridizes to the nucleic acid of SEQ ID NO:25 or 27. The nucleic acid comprising SEQ ID NO:23, 25 and 27 were grouped into distinct Groups III, IV and V respectively, in paper number 8 (10/4/000). Therefore, the use of each individual nucleic acid comprising SEQ ID NO:23, 25 or 27 is also considered distinct. The nucleic acid of Groups III-V are distinct for reasons of record, see paper number 8. Accordingly, these claims are subject to restriction under U.S.C.§ 121. Further a search of SEQ ID NO:23, 25 and 27 and all the possible nucleic acids that would hybridize to said nucleic acid and encode a T-type calcium channel would not be co-extensive particularly with regard to the literature search. An examination of the materially different, patentably distinct inventions

in a single application would constitute a serious undue burden on the examiner. The requirement is still deemed proper and is therefore made FINAL.

Response to Applicants Arguments

3. The rejections of record under 35 U.S.C. 112, second paragraph, in paper number 22 are withdrawn in view of applicants arguments and amendments filed in paper number 23 (10/8/02).

4. The rejections under 35 U.S.C. 101 and 112, first paragraph are maintained for reasons of record in paper number 22.

Applicant argues: a) the invention claimed is a method to identify agonists and antagonists of the calcium ion channels and there is no assertion that the channels themselves or the nucleotides encoding them are candidates as pharmaceutics for treating deceases, it is the agonists or antagonists of these channels which have an effect on the activity of the endogenous calcium ion channels in a subject to be treated, b) the channels themselves and the nucleic acids containing nucleotide sequences encoding them are research and screening tools to identify such agonists and antagonists. Further applicant, states "The real question is: What are the conditions that are treatable by the agonists or antagonists that would be identified by the presently claimed methods? For starters, these conditions are identified in the specification as epilepsy, migraine, ataxia, schizophrenia, hypertension, arrhythmia, angina, depression, small lung carcinoma, Albert-Eton syndrome and Parkinson's disease". Also applicant argues other patents have issued directed to nucleotide sequences encoding T-type channels". Applicants arguments have been fully considered but not found persuasive. The ion channel encoded by the nucleic acid of SEQ ID NO:23 and the ion

channels encoded by a nucleotide which hybridizes to the nucleic acid of SEQ ID NO:23 have not been disclosed to involved in a specific disease state. There is no showing in the art that a specific T-type calcium channel is involved all the disease state of epilepsy, migraine, ataxia, schizophrenia, hypertension, arrhythmia, angina, depression, small lung carcinoma, Albert-Eton syndrome and Parkinson's disease. Although the T-type calcium ion channel of SEQ ID NO:23 may be involved in one or more of the aforementioned disease states further experimentation is required to determine which disease state, if any, is result of said T-type calcium ion channel dysfunction. Further there is no disclosure as to which T-type calcium ion channel encoded by a nucleotide which hybridizes to the nucleic acid of SEQ ID NO:23 would be involved in the disease state of epilepsy, migraine, ataxia, schizophrenia, hypertension, arrhythmia, angina, depression, small lung carcinoma, Albert-Eton syndrome and Parkinson's disease. Just because a nucleic acid hybridizes to the polynucleotide of SEQ ID NO:23 does not automatically mean it will encode a protein that will be involved in the afore mentioned disease states. Again further experimentation is required to determine a function. Further there is no disclosure of a even a single agonist or antagonist identified by claimed method that will act as an antagonist or agonist to treat the diverse diseases claimed as possible targets. There is no disclosure of whether an agonist as compared to an antagonist will treat a specific disease. Therefore, again further experimentation is required to find a compound that will bind to the T-type calcium ion channel used in instant methods and correlate it with a disease state. The utilities asserted by Applicant are not substantial or specific. Neither the specification nor the art of record disclose any disease states treatable by the agonists and antagonists identified by the

method of instant invention. Similarly, neither the specification nor the art of record disclose any instances where blocking any effects of T-type calcium ion channel of SEQ ID NO:23 or ion channel encoded by a nucleotide which hybridizes to the nucleic acid of SEQ ID NO:23 would reduce the effect of a disease state. Thus the corresponding asserted utilities are essentially methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use especially when the complete sequence of the claimed invention is not known. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the disclosed polynucleotides/polypeptides/ agonists/antagonists, further experimentation is necessary to attribute a utility to the disclosed polynucleotides and encoded polypeptides. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Since the utilities asserted by Applicant for polynucleotide and polypeptide of instant application are not substantial or specific, then it follows that the method of claim 25-31 (method of identifying compounds capable of acting a s agonists or antagonists for T-type mammalian calcium channels), also has no utility. Similarly, agonists and antagonists identified by said method have no utility.

Further, applicant's reference to Patent Number 6,096,514; 6,090,623; 6,013,474; 5,876,985 as establishing a patentable utility for the claimed protein is not persuasive because each application is examined on its own merits. In the decision of *In re Hutchison*, 69 USPQ 138 (CCPA, 1946), the court held that

> "We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the six article claims on appeal were properly rejected below, and this we pass upon without further reference to, and without comparing them with, the claims in the patent or the claims which stand allowed in this application."

In essence, the position in the instant application that each application is examined on its own merits can be found in the judicial precedent cited above. The rejections in the instant application will only be withdrawn if they are shown to be legally or factually unsound.

In conclusion, claim 26,29 remain rejected under 35 U.S.C. 101/35 U.S.C. 112, first paragraph, for reasons of record in paper number 22; amended claims 25, 27, 28, 30 and 31 (claims amended to overcome rejection under 35 U.S.C. 112, second paragraph) are also rejected under 35 U.S.C. 101/35 U.S.C. 112, first paragraph, for reasons of record in paper number 22. Although claims 25, 27, 28, 30 and 31 have been amended the issues are essentially the same as those addressed in paper number 22. Therefore, claims 25-31 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims remain 25-31 rejected under 35 U.S.C. 112, first paragraph (for reasons of record in paper number 22). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
May 3, 2003

YVONNE EYLER, PH.D
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